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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,591	12/04/2001	Franco Castellini	BUG 2 0150	5163

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,591

Applicant(s)

CASTELLINI, FRANCO

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2001 and 07 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 30-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-29, in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 30-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 5.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. The information disclosure statement filed 16 July 2002 has been considered and made of record.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of the claim cannot be clearly determined in view of the instant claim language. It is not entirely clear from the instant claim language as to whether a biofilm detecting device is being claimed or a biofilm-detecting device in combination with the dental unit recited in the claim. Since the last lines of the claim recite that at least one conduit is equipped with means for detecting the presence of the biofilm, the claim will be examined on its merits as though the combination is claimed. Clarification and/or correction are requested.

In claims 2 to 4, the exact structure being claimed is not clear. Mere statement that the detecting means are of the direct detection type that uses an appropriate substance or fluid to cause an alteration of the biofilm is not clear. Note an optical detection unit is capable of detecting the presence of a film and/or the responses of a film to a reagent. Does this claim language include additional structure such as a reagent dispensing system?

In claim 5, it is not clear what structural limitation is intended by the claim language "there being a reagent or coloring fluid acting on the sampling element". If the detection means is indirect, is the sample element contacted with the fluid after removal from the device?

In claim 10, "the transparent conduit portion" and "the reagent or coloring fluid" lacks antecedent basis. Note claim 1 is silent as to the use of such an agent.

In claim 13, "the reagent substance" lacks antecedent basis. Note claim 1 is silent as to the use of such an agent.

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In claim 28, "the balls" lacks antecedent basis. Note claim 28 depends from claim 25, which depends from claim 5. Both claims 25 and 5 are silent with respect to the presence of balls. Claim 24 recites the presence of balls.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Banks et al.(EP 0 531 067) or Siebel et al.(US 4,912,332) in view of Fitton (US 6,106,771).

The reference of Banks et al. discloses a device for detecting the presence of biofilm on the surfaces of conduits. The device includes a light emitter (34) and detector (18).

The reference of Siebel et al. discloses a device for detecting the presence of biofilm on the surfaces of conduits. The device includes a light emitter (5) and detector (11).

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While the references disclose using the device for conduits in process streams, the reference is silent as to the use of the device on a conduit of a dental unit.

The reference of Fitton discloses that scale and biofilms are a concern in the waterlines of dental units (See the entire disclosure).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the detection system of the reference of Banks et al. or Siebel et al. in a conduit of a dental unit for the known and expected result of providing a means recognized in the art for detecting biofilms in conduits which is a concern in the waterlines of dental units as evidenced by the reference of Fitton.

With respect to the location of the detector with respect to the waterlines of the dental unit (claim 23), it would have been obvious to one of ordinary skill in the art to determine the optimal position while providing an indication of contamination. One of ordinary skill in the art would recognize that any water flow which comes into contact with the patient would be of concern with respect to contamination as opposed to fluids used to merely rinse a sink of the dental unit.

10. Claims 2-4, 6, 7 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Banks et al.(EP 0 531 067) or Siebel et al.(US 4,912,332) in view of Fitton (US 6,106,771) and taken further in view of Tuompo et al.(US 5,910,420).

The combination of either Banks et al. or Siebel et al. with the reference of Fitton has been discussed above.

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The above claims differ by reciting that the system includes structure for introducing a reagent with reacts with the biofilm to be detected.

The reference Tuompo et al. discloses that the use of chemical reagents with biofilms form on the surface of a conduit is known in the art (See column 2, lines 11-42).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a chemical reagent in the system of the modified primary references for the known and expected result of providing an alternative means recognized in the art to achieve the same result. Use of chemical reagents with respect the optical detectors of the primary references would allow one of ordinary skill in the art to distinguish biological films from other films such as scale.

When using chemical reagents as suggested above, it would have been obvious to one of ordinary skill in the art to determine the optimum wavelength of light to employ based merely on the specifics of the reagent employed while allowing the color to be detected by the optical detection system. With respect to the use of a control signal, the use of control signals is known in the art for subtracting background noise and/or calibration of the detection signal.

With respect to the use of a means for dispensing reagent, it would have been obvious to one of ordinary skill in the art to provide a means for adding reagent (inlet port and reagent reservoir, pump, etc.) for the known and expected result of providing the reagent within the conduit which is required of the test suggested by the reference of Tuompo et al.

With respect to the use of an electrical properties detector, the reference of Tuompo et al. also discloses that electric conductivity is known in the art for the detection of biofilms (See column 2, lines 20-22).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ an electrical conductivity sensor in the waterlines on a dental unit for the known and expected result of providing an alternative means recognized in the art to achieve the same result, detection of biofilms on the surfaces of conduits. In the absence of a showing of criticality and/or unexpected results, the use of a resistance sensor or conductivity sensor would have been within the purview of one having ordinary skill in the art since one is merely a reciprocal of the other.

With respect to the presence of an altering means, the reference of Siebel et al. discloses that it is known in the art to provide a signal so as to trigger the addition of deposit removing means (See column 5, lines 27-31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to determine the optimal triggering signal based merely on the means employed for removing the deposit. The use of audible or visual displace signals would have been obvious when the method of removal employs manual steps such as cleaning, adding reagents or replacing conduits.

11. Claims 5, 25, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Banks et al.(EP 0 531 067) or Siebel et al.(US 4,912,332) in view of Fitton (US 6,106,771) and taken further in view of Schapira et al.(US 5,249,874).

The combination of either Banks et al. or Siebel et al. with the reference of Fitton has been discussed above.

The above claims differ by reciting that the detector is a removable component.

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The reference of Schapira et al. discloses a device for the detection of biofilms in a conduit that employs a removable element (19).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a detection device as disclosed by the reference of Schapira et al. in the system of the modified primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, detection of a biofilm in dental unit conduit. Use of the Schapira et al. device would not require the use of any complex electronic components.

Note the test device includes a housing unit (7,3) that allows the test element to be positioned within the conduit while permitting normal flow of fluid through the conduit.

With respect to whether or not the housing unit is integral or disposable (removable), it is well established that whether an element is integral or separable is not a patentable distinction and is merely an obvious matter in design choice that it within the level of one having ordinary skill in the art (See *In re Larson*, 144 USPQ 347 (CCPA 1965) and *In re Dulberg*, 129 USPQ 348 (CCPA 1961)).

Allowable Subject Matter

12. Claims 8, 9, 21, 22, 24, 28 and 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

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With respect to claims 8, 9 and 21, while the prior art of record suggests adding reagent to the conduits to contact the biofilm, the prior art of record fails to teach or fairly suggest the combination of elements recited in these claims for allowing the test liquid to be remove, recirculated and/or isolated within a test portion of the dental unit conduit.

With respect to claim 24, the prior art of record fails to teach or fairly suggest the use a plurality of balls of the same material as the test conduit as a sensing element for biofilms.

With respect to claims 28 and 29, the prior art of record fails to teach or fairly suggest a detection device which includes a plurality of balls and is constructed such that the balls can be removed one at a time and filled with a biofilm reagent such that the ball is contacted with a color changing reagent when removed from contact with the flow of fluid in the conduit.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

All of the following prior art references are cited as prior art which pertains to the detection of biofilms in liquid flow systems:


Sauer et al.(US 5,049,492) ; Davies (US 5,285,162) ; Dirk (US 5,488,856) ; Pierson et al.(US 6,498,862) ; Spiekermann (DE 19633808) ; Kawai et al.(JP 11-169876) ; Aquas (JP 2000-126781) ; and Lipskier (WO 97/12990).

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB
April 21, 2003